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## Important safety information

**Bridge occlusion balloon**

The Bridge occlusion balloon is indicated for use for temporary vessel occlusion of the superior vena cava in applications including perioperative occlusion and emergency control of hemorrhage. Use of the Bridge occlusion balloon in procedures other than those indicated is not recommended.

The adverse events associated with an occlusion balloon procedure include, but are not limited to allergic reactions, death, embolization, hematoma, hemorrhage, sepsis/infection, short-term hemodynamic deterioration, thromboembolic episodes, vascular thrombosis, vessel dissection, vessel perforation, vessel spasm.

In order to facilitate rapid delivery, it is recommended that a guidewire is in place in the superior vena cava prior to beginning the lead extraction procedure. Attempting to place the guidewire after a tear has occurred may:

- Result in an inability to traverse the superior vena cava with the guidewire
- Result in the guidewire exiting the vasculature at the tear site
- Result in an inability to place the Bridge occlusion balloon catheter
- Delay or prevent the ability to achieve occlusion

This information is not intended to replace a discussion with your healthcare provider on the benefits and risks of this procedure to you.

**GlideLight laser sheath**

The GlideLight laser sheath is intended for use with other lead extraction tools in patients who are suitable candidates for removal of implanted pacemaker and defibrillator leads. The use of the GlideLight laser sheath may be unsafe in some patients, or with certain leads, or when the leads cannot be extracted through the superior veins (that is, when groin or surgical extraction is required). Rarely a patient undergoing lead extraction may require urgent surgical treatment for a complication; therefore, patients should not undergo lead extraction with a laser sheath in centers where emergency surgical procedures cannot be performed. Leads not intended for extraction may be damaged during the procedure and may require replacement. Ask your doctor if you are a candidate for lead extraction with the GlideLight laser sheath.

Potential minor adverse events associated with lead extraction procedures that may or may not require medical or surgical treatment include: a tear or damage to the blood vessels, the heart or its structures; bleeding at the surgical site; or collapsed lung.

Rare but serious adverse events that require emergency medical or surgical procedures may include: a tear or damage to the blood vessels, the heart, lungs or their structures; blood clot or obstruction of the blood vessels or lungs by debris or lead fragments. Other serious complications may include: irregular heartbeat, weakened heart muscle, infection, respiratory failure or complications associated with anesthesia, stroke or death.

This information is not intended to replace a discussion with your healthcare provider on the benefits and risks of this procedure to you.

**Caution:** Federal law restricts this device to sale by or on the order of a physician.


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PHILIPS

Lead Management

# Risks and considerations

of cardiac lead extraction

# Risks of capping a lead

**Increased risk of infection**[2,3,4]

- Increased risk of infection five years post-procedure[1]
- Risk of infection increases 2-7% at each device change[2]

**Worse outcomes and increased difficulty of future extraction**

- 2.6 times more likely to have a major adverse event (MAE)[3]
- 4 times more likely to have infected lead material retention, leading to a 2x increase in one-month mortality[3]
- Risk of failed lead removal doubles every three years[4]

**Increased risk of venous occlusion and tricuspid regurgitation**[5,6]

- Can prevent access for new leads
- Risk of increased tricuspid regurgitation and resulting atrial fibrillation or right-sided heart failure

**MRI contraindication**[7]

- 75% of device patients will need an MRI in their lifetime[8]
- Abandoned leads are a risk for tissue damage or inappropriate cardiac stimulation[7]

# Considerations of lead extraction

**Extraction safety at device upgrade**[9]

- Less complex and more likely to be successful, with a 97.2% clinical success rate
- Lower complication rates, despite significantly worse clinical profiles, with a 0.4% mortality rate and a 1% MAE rate

**Overall procedural safety of lead extraction**[2]

- Laser-assisted lead extraction is clinically proven safe, with a 97.7% clinical success rate, 1.4% procedural MAE rate, and 0.28% procedural mortality rate[10]

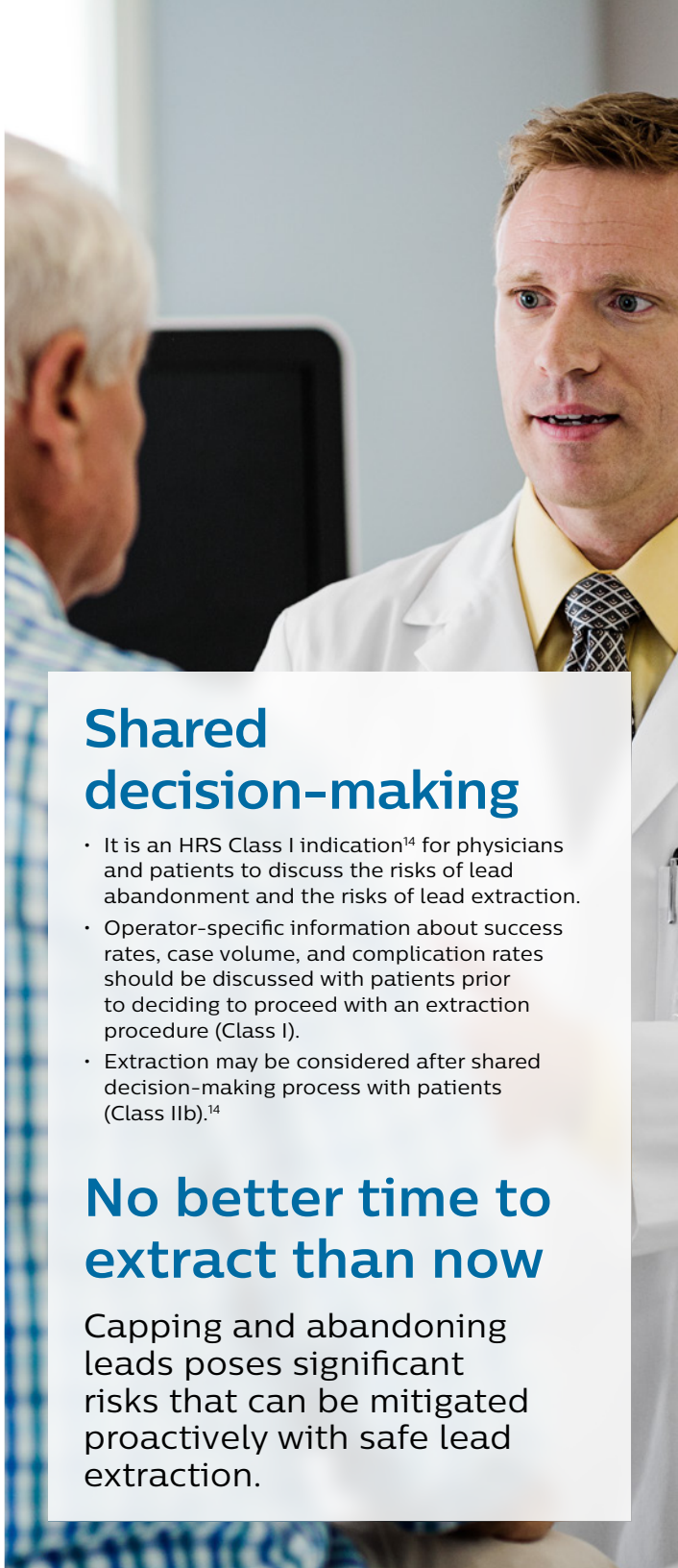
**New innovations designed for safety**

- In the rare event of an superior vena cava (SVC) tear, the Philips Bridge occlusion balloon can reduce blood loss by 90%[11] on average and provide 30 minutes of acceptable hemostasis[12]
- With proper use of the device, SVC tear survival has gone from 56.4% to 91.7%[13]

Overall, lead extraction has a

**99.72%**

procedural survival rate[10]



# Shared decision-making

- It is an HRS Class I indication[14] for physicians and patients to discuss the risks of lead abandonment and the risks of lead extraction.
- Operator-specific information about success rates, case volume, and complication rates should be discussed with patients prior to deciding to proceed with an extraction procedure (Class I).
- Extraction may be considered after shared decision-making process with patients (Class IIb).[14]

# No better time to extract than now

Capping and abandoning leads poses significant risks that can be mitigated proactively with safe lead extraction.